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09/685,403	10/10/2000	Peter R. Beetham	7991-086	4644

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

23

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/685,403

Applicant(s)

BEETHAM ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 14-18, 20-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 14-18, 20-23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement (PTO-1449) (Page \_\_\_\_\_)
- 4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)

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### **STATUS OF THE APPLICATION**

1. This Office action is in response to Applicant's amendments and remarks filed 17 March 2003.
2. Claims 1-3 and 19 have been cancelled without prejudice.
3. New claims 25-28 have been added.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
5. Those rejections under 35 USC 102(e, f and g) and Double Patenting are now moot. Applicant states that pending US Patent Application 09/424,344 has been abandoned (page 6 of the Remarks). No continuation, continuation-in-part or divisional application appears to have been filed claiming priority to application 09/424,344 under 35 USC 120 or 121.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Drawings***

7. New corrected drawings are required in this application as indicated by the Draftsman's notice attached hereto. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for

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***Claim Rejections - 35 USC § 112***

8. Claims 14-18, 20-23 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method for producing a non-transgenic herbicide resistant or tolerant plant comprising introducing to a plant cell a recombinagenic oligonucleobase to produce a mutant EPSPS gene.

Applicant teaches a method of producing a herbicide resistant or tolerant *Arabidopsis* EPSPS protein by introducing an *Arabidopsis* gene encoding a wild-type EPSPS protein into *Salmonella typhi* and introducing a recombinagenic oligonucleobase into the bacterium cell to produce a mutant EPSPS gene (see 6.1.5 on page 22 of the specification).

Applicant does not teach the claimed method in a plant or a herbicide resistant or tolerant plant produced thereby. The results at 6.2 on page 23, paragraph 2, are unclear as to whether the procedure was applied in *Arabidopsis* or if the modified EPSPS gene produced in the bacterium was introduced by transgenic means into the *Arabidopsis* plant and that said plant was herbicide resistant or tolerant.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight

necessary to practice an invention. These factors are: the quantity of experimentation

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necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has not provided a working example of the claimed method in plants. The state of the art at the time of Applicant's invention was such that the claimed method had not been proven in introducing point mutations *in vivo* into a plant genome in a predictable manner. The nature of the invention is such that extensive guidance would have been required in terms of what recombinagenic oligonucleobases to use for which plant to mutate which site in a given gene target. The art teaches that the claimed method can be highly unpredictable as to what actual mutation would be introduced into a target site and suggests that predictability can be highly site specific. The claim method has proven to be far less predictable when used in plants than when the same method is used in mammalian cells, for example (Zhu *et al* 1999, PNAS-USA 96:8768-8773, see Table 2 on page 8771, and page 8772, right column, paragraph 2)(Rice *et al* 2000, Plant Physiology 123:427-437, see the Abstract on page 427). Because of the absence of working examples, state of the art, nature of the invention and unpredictability of the art, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to design a myriad of recombinagenic oligonucleobases to modify any plant EPSPS gene at the

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would be operable in producing a non-transgenic herbicide resistant or tolerant plant comprising a mutant EPSPS gene, as broadly claimed.

This rejection is repeated for the reason of record in the Office action mailed 13 February 2002. The Examiner has reconsidered Applicant's arguments in the response filed 18 June 2002, and addresses those arguments here.

Applicant argues that Applicants merely used an *in vitro* bacterial expression system to demonstrate that the gene products of the *Arabidopsis* mutant genes are in fact glyphosate resistant and that the mutant *Arabidopsis* clones expressed the mutant protein at substantially the same level as the wild-type protein (page 5 of the 18 June 2002 response). Applicant argues that Zhu *et al* and Rice *et al* show that this technology works fine in this art and that these two articles demonstrate that the Applicants have enabled the present claims (paragraph spanning pages 5-6 of the 18 June 2002 response). Applicant argues that under the US Patent Law, Applicants' duty is to teach how to practice the claimed invention and Applicant is unaware of any requirement that specify the duty to carry out specific experiments in order to obtain a US Patent (page 6 of the 18 June 2002 response). Upon reconsideration of Applicant's arguments the Examiner does not find them persuasive. The *Wands* factors clearly take into consideration the presence of working examples of the claimed invention. In addition, the amount of guidance present, the nature of the invention, the state of the prior art and the predictability or unpredictability of the art. In the instant case, Applicant

targeted mutations are not produced in a predictable manner (see Table 2 on page

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8771). Hence, it remains unclear that Applicant has adequately enabled the method as broadly claimed.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

### ***Claim Rejections - 35 USC § 103***

9. Claims 14-18, 20-23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kmiec (U.S. Patent 5,756,325), filing date September 9, 1996, in view of Hawkes *et al* (WO 98/54330) and Applicant's admission.

The teachings of Kmiec can be found in the Office action mailed 13 February 2002.

Kmiec does not teach a method of producing a non-transgenic herbicide resistant or tolerant plant by mutating *in vivo* an endogenous EPSPS gene to encode the claimed

The teachings of Hawkes *et al* can be found in the Office action mailed 13 February 2002. Hawks also teaches that by comparing the sequences obtained from 'high EPSP synthase expression' lines of plants, cultivars or plant cells with appropriate unselected controls the specific mutation(s) responsible for conferring high expression of EPSP synthase will be identified (page 8, 1<sup>st</sup> paragraph).

Applicant admits that the mutations introduced by the claimed method were known in the art prior to Applicant's invention (page 2 of the specification).

Hence it would have been *prima facie* obvious to one of ordinary skill in the art to modify the teachings of both Kmiec and Hawkes to introduce other mutations in an EPSP synthase plant gene *in vivo* that were known in the art at the time of Applicant's invention. The teachings of Hawkes would have given one of skill in the art a reasonable expectation of success in modifying the method of Kmiec to modify plant EPSPS gene *in vivo* to produce herbicide tolerant, non-transgenic plants.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.



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**Conclusion**

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.  
2 June 2003

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